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10/566,873	07/03/2006	Rachel Butler	029312-9008-US00	9573
23409	7590	08/16/2011	EXAMINER	
MICHAEL BEST & FRIEDRICH LLP			NEGRELLI, KARA B	
100 E WISCONSIN AVENUE			ART UNIT	PAPER NUMBER
Suite 3300			1766	
MILWAUKEE, WI 53202				
NOTIFICATION DATE		DELIVERY MODE		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/566,873	<b>Applicant(s)</b> BUTLER ET AL.
	<b>Examiner</b> KARA NEGRELLI	<b>Art Unit</b> 1766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 16 June 2011.  
 2a) This action is **FINAL**.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-6,10,12-20 and 23-30 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-6,10,12-20 and 23-30 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-448)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Amendment*

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Any new grounds of rejection set forth below are necessitated by applicant's amendment filed on June 16, 2011. In particular, claim 1 has been amended to recite "...wherein the water-soluble polymeric material is one or more chosen from the group consisting of water-soluble polysaccharides and water-soluble vinyl polymers, and..." Claims 1-6, 10, and 17-20 have been amended to correct dependency. Claim 7 has been amended to recite "...wherein the water-soluble polymeric material is selected from one or more of the following group of materials: poly(vinyl alcohol) and dextran." Claim 23 has been amended to remove the limitation "in less than 107 seconds" in order to overcome a new matter rejection. Claim 26 has been amended to recite "...said water-soluble polymeric material being one or more chosen from the group consisting of water-soluble polysaccharides and water-soluble vinyl polymers..."
3. It is noted that MPEP 706.07 a) states that "Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims, nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p)." Thus, the objection below does not introduce a new ground of rejection, and this action is properly made final.

4. It is noted that the newly introduced limitations were not present at the time of the preceding action. For this reason it is proper to make the present action FINAL.

***Specification***

5. The amendment to the specification filed November 18, 2011 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The specification has been amended to delete particular applications of the porous material of the this invention. Specifically, the specification has been amended to delete tissue scaffolding, absorbents, scaffolds for sensor materials, wound healing matrices, and scaffolds for combinatorial chemistry from paragraph [0026] of the specification. Deletion of these terms broadens the scope of the originally filed application and thus constitutes new matter.

Applicant is required to cancel the new matter in the reply to this Office Action, and these terms must not be deleted.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by Butler et al. Advanced Materials, "Emulsion Templating Using High Internal Phase Supercritical Fluid Emulsions."

8. Butler et al. (2001) (*Advanced Materials 2001, 13, 1459-1463*) teaches CO<sub>2</sub>-in-water emulsions without the use of any volatile organic solvents, just water and CO<sub>2</sub> (column 1, last line of the first full paragraph). The CO<sub>2</sub>-in-water emulsions comprise 70% to 80% CO<sub>2</sub>, 10% w/v poly (vinyl alcohol) which the water soluble polymeric material of instant claim 26, and 1 to 10% surfactant w/v based on water (page 1460, column 2, paragraph 2, lines 1-4 and page 1461, paragraph 2, lines 5-8). While Butler et al. teach that crosslinked acrylamide based polymers may be used to produce the porous materials, Butler et al. further teach acrylamide may be substituted with 2-hydroxyethyl acrylate. The substitution of acrylamide with 2-hydroxyethyl acrylate led to porous, open-cell materials suggesting that the technique described by Butler may be applied to a wide range of hydrophilic and hydrogel materials. Butler also teaches that water-soluble materials are desirably used in the formation of the materials of the invention, see page 1460, third full paragraph. Hydroxy-ethyl acrylate is described in the instant specification as a water-soluble matrix building material. See page 6, first paragraph of the instant specification.

9. The porous materials of Butler, which may comprise identical amounts of identical materials as described in instant claim 26, will inherently possess the same properties, including the ability to substantially fully dissolve in water at 20°C. MPEP 2112 states "When the PTO shows a sound basis for believing that the products of the

applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The burden is shifted to applicant to provide evidence that Sample 4 of Butler et al., in which crosslinked acrylamide is substituted with 2-hydroxyethyl acrylate, will not possess the property of being able to substantially fully dissolve in water at 20°C.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-6, 10, 12-20, and 23-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ko et al. (US 2003/0134918) and further in view of Butler et al. Advanced Materials, "Emulsion Templating Using High Internal Phase Supercritical Fluid Emulsions."

12. The rejection is adequately set forth in paragraphs 9-28 of the Office Action mailed on March 16, 2011, the rejection of which is incorporated herein.

13. It is additionally noted that Claim 1 of Ko et al. teaches a method of making an absorbent foam, in which no crosslinking agent is present or required. Thus, Ko et al. teach an embodiment of an absorbent foam which is substantially free of crosslinking.

***Response to Arguments***

14. Applicants' arguments filed on June 16, 2011 with regards to the rejection of claims 1-6, 9-10, 12-20, and 23-30 under 35 U.S.C 112, first paragraph, are moot in view of the amendments to the claims, which cancel the new matter limitations.
15. Applicant's arguments filed June 16, 2011 have been fully considered but they are not persuasive. Applicant argues that paragraph [0022] of Ko et al. suggests that in the event that the polymer does not itself undergo self-crosslinking, a crosslinking agent is added in order to initiate crosslinking of the polymer. Applicant argues that the passage from paragraph [0022] would not lead one of ordinary skill in the art to envision materials that are water soluble and free from crosslinking, particularly when one considers the reference as a whole.
16. Applicants' argument is not persuasive. As discussed in the rejection above, Claim 1 of Ko et al. teaches a method of making an absorbent foam, in which no crosslinking agent is present or required. Thus, Ko et al. teach an embodiment of an absorbent foam which is substantially free of crosslinking. Ko et al. explicitly teach that water solubility rests upon the degree of crosslinking within a material and further teaches that crosslinking tends to render a material water insoluble (see paragraph [0016]).
17. Claim 1 of Ko et al. teaches a method for producing an absorbent foam comprising combining water and a supercritical fluid phase comprising effective amounts of at least one super-absorbent monomer, wherein an oxidizing initiator is

present in either of the water or super-critical phase, and a reducing initiator is present in the other of the water or super-critical phase, wherein the super-critical phase and the water phase form an emulsion, such that polymerization of at least one superabsorbent precursor monomer takes place in the water phase to form polymerized materials. In this embodiment of claim 1, no crosslinking is recited or required. Paragraph [0008] of Ko et al. teaches that the super-critical phase may comprise carbon dioxide, and thus a C/W emulsion is formed, as is required by instant claim 1. After polymerization, the carbon dioxide is easily vented away as a gas. By controlling the nature of the emulsion, and the polymerization process, pores are created in a polymer matrix. Generally, the monomers which are used to produce the super absorbent polymer are water-soluble (paragraph [0018] of Ko et al.). A specific objective of Ko et al. is to produce more water-soluble, environmentally friendly foams (paragraph [0007]).

18. The water phase comprises an emulsifier (surfactant), as is required by instant claim 1. Ko et al. explicitly teach that in an embodiment of the invention, the solvent (supercritical fluid) may be freeze-dried, in which the material is first frozen and then sublimed, wherein the solvent passes directly into the vaporized state. It is again noted that Ko et al. teach that in embodiments wherein carbon dioxide is used as the supercritical fluid, the supercritical fluid is easily vented away. Ko et al. further teach the use of surfactants such as polyoxyethylene sorbitan monolaurate and polyoxyethylene sorbitan monopalminate (Tween 40) (paragraph [0021]). Further additives can also be used in the composition, such as solid metal nanoparticles (pertaining to instant claims 2-6 and 19-20), such as hydrophilic titanium oxide, silica, and the like (paragraph

[0048]), as well as copper hydroxide or zinc hydroxide (organic reagents) as antimicrobial and/or odor control agents (paragraph [0065]).

19. As to applicants' argument regarding paragraph [0055] of Ko et al., it is again noted that Claim 1 of Ko et al. teaches a method for producing an absorbent foam comprising combining water and a supercritical fluid phase comprising effective amounts of at least one super-absorbent monomer, wherein an oxidizing initiator is present in either of the water or super-critical phase, and a reducing initiator is present in the other of the water or super-critical phase, wherein the super-critical phase and the water phase form an emulsion, such that polymerization of at least one superabsorbent precursor monomer takes place in the water phase to form polymerized materials. In this embodiment of claim 1, no crosslinking is recited or required. Paragraph [0008] of Ko et al. teaches that the super-critical phase may comprise carbon dioxide, and thus a C/W emulsion is formed, as is required by instant claim 1. After polymerization, the carbon dioxide is easily vented away as a gas. Even when the Ko reference is read in its entirety, there is an embodiment in which crosslinking is not present or required.

20. With regards to water-soluble or water-insoluble, Examiner agrees that these terms are defined in paragraph [0030]. Water-soluble materials are described as being free from a substantial degree of crosslinking. Claim 1 of Ko et al. teaches a method for producing an absorbent foam comprising combining water and a supercritical fluid phase comprising effective amounts of at least one super-absorbent monomer, wherein an oxidizing initiator is present in either of the water or super-critical phase, and a reducing initiator is present in the other of the water or super-critical phase, wherein the

super-critical phase and the water phase form an emulsion, such that polymerization of at least one superabsorbent precursor monomer takes place in the water phase to form polymerized materials. In this embodiment of claim 1, no crosslinking is recited or required.

21. As to applicants' argument regarding freeze-drying, it is noted that it is known in the art that in the invention of Ko et al., the supercritical fluid is the solvent. This is evidenced by the fact that 1) Ko et al. specifically teach venting away of carbon dioxide in a C/W emulsion (paragraph [0008]) and the further express teaching that the states "For freeze drying embodiments, the solvent used...needs to be capable of first freezing and then capable of undergoing sublimation, wherein the solvent passes directly from its frozen state to a vapor state," at paragraph [0032]. This is not merely a definition as asserted by the applicant, as the statement clearly teaches embodiments of freeze-drying and does not merely state what takes place in freeze-drying in general. Regardless of the fact that other methods of removing solvent are disclosed in Ko et al., this does not negate a finding of obviousness under 35 USC 103 since a preferred embodiment such as an example is not controlling. Rather, all disclosures "including unpreferred embodiments" must be considered. In re Lamberti 192 USPQ 278, 280 (CCPA 1976) citing In re Mills 176 USPQ 196 (CCPA 1972). Therefore, it would have been obvious to one of ordinary skill in the art to utilize a freeze drying process to remove carbon dioxide given that 1) Ko et al. explicitly teaches that a method of making an absorbent polymeric foam using carbon dioxide as a super critical fluid which completely replaces oil in an oil-in-water emulsion and 2) explicitly teaches that in

**embodiments** which employ freeze drying, this solvent is vented away. Regardless of the fact that paragraph [0044] may not mention freeze drying, paragraph [0032] specifically states that in **embodiments** employing freeze drying, the solvent is first frozen and then vented away.

22. Applicants' argues that the examiner has improperly imported teachings from the instant specification into the instant claims. This is not the case. What the examiner is demonstrating is that the end uses of the products of the instant invention may be identical to those of Ko et al. The instant specification contradicts applicants' argument that "water-soluble porous, polymeric material would not be useful in applications that require absorbent materials (e.g. bandages or wound dressings) as they would dissolve upon exposure to an aqueous medium." The instant specification provides evidence that porous, water-soluble polymers may be used in absorbents and wound healing matrices. If this were not true, there exists an enablement issue within the instant specification, given that the instant specification explicitly teaches that the water-soluble porous materials of the instantly claimed invention may be used to produce absorbents. See page 10, lines 1-2 of the first full paragraph and line 4 of the first full paragraph). Furthermore, solubility (in water) of polymeric materials is affected by a number of factors, such as temperature and length of exposure.

23. The examiner has not improperly imported teachings from the instant specification into the instant claims. The examiner has demonstrated that the instant specification explicitly and unambiguously teaches that the porous materials of the invention may be used as both wound healing matrices and absorbents, so as to

provide evidence that applicant is incorrect in stating that "water-soluble porous, polymeric material would not be useful in applications that require absorbent materials (e.g. bandages or wound dressings) as they would dissolve upon exposure to an aqueous medium." It is noted that deletion of these applications from the specification constitutes new matter, as described in the objection to the specification above.

24. Regarding instant claim 26, the claim is addressed in the rejection above.
25. As to applicants' arguments regarding the rejection of claims 12, 16, and 23-30 as obvious over Ko et al. (US 2003/0134918) and further in view of Butler et al. Advanced Materials, "Emulsion Templating Using High Internal Phase Supercritical Fluid Emulsions," the discussion above with regards to Ko et al. is incorporated herein.
26. For the reasons provided above, applicants' arguments regarding Ko et al. and Butler et al. are not persuasive.

#### *Conclusion*

27. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
28. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARA NEGRELLI whose telephone number is (571)270-7338. The examiner can normally be reached on Monday through Thursday 9:30 am EST to 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on (571)272-1302. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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